DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 8,2015

NovaBone Products, LLC
Ms. Lisa Simpson
Manager, Regulatory Affairs
13510 NW US Highway 441
Alachua, FL 32615

Re: K142712
Trade/Device Name: Dental Collagen Wound Dressing (Nova Tape and NovaPlug)
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 11, 2014
Received: December 12, 2014

Dear Ms. Simpson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142712

Device Name

Dental Collagen Wound Dressing (NovaTape and NovaPlug)

Indications for Use *(Describe)*

Dental Collagen Wound Dressings (NovaTape and NovaPlug) are intended for the management of oral wounds and sores, including:

- Denture sores
- Oral Ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites
- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY – NovaTape & NovaPlug

DRIVING INNOVATION IN OSTEOBIOLOGICS

Date Prepared: January 5, 2015

510(k) Holder / Submitter:

Name: NovaBone Products, LLC
Address: 13510 NW US Highway 441
Alachua, FL 32615

Telephone: (386) 462-7661, ext. 216
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Contact: Lisa Simpson
Manager, Regulatory Affairs

Name of Device:

Trade Names: NovaTape (NT)
NovaPlug (NP)
Common Name: Dental Collagen Wound Dressing
Regulation Number: None
Regulation Name: None
Regulatory Class: Not Classified
Product Code: KGN

Legally Marketed Predicate Devices:

K040403 Collagen Matrix
Collagen Topical Wound Dressing - Oral

Device Description:

Dental Collagen Wound Dressings are soft, white to off-white, resorbable collagen dressings produced from cross-linked, purified collagen derived from bovine hide. The thickness and pore structure of the device allow it to absorb fluids and blood at the defect site. Dental Collagen Wound Dressings are supplied sterile, non-pyrogenic, and are for single use only.

Intended Use / Indications for Use

Dental Collagen Wound Dressings (NovaTape and NovaPlug) are intended for the management of oral wounds and sores, including:

- Denture sores
- Oral Ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites
- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

Technological Characteristics and Substantial Equivalence:

The proposed NovaTape / NovaPlug (NT/NP) Dental Collagen Dressings are substantially equivalent to the predicate Collagen Topical Wound Dressings – Oral (K040403). The predicate devices are marketed as under the name "ACE Resorbable Collagen Tape (RCT) & ACE Resorbable Collagen Plug (RCP)". The predicate and proposed devices have the same clinical indications for use.

Design / Mode of Action

The predicates (K040403) and proposed NT/NP dental collagen wound dressings are composed solely of collagen and both are provided in tape and plug formats. The dressings act to absorb moisture from the oral wound site, thereby maintaining a moist environment. The dressings resorb within approximately 14 days of implantation. Because the basic design technology and mode of action are similar between the predicate the proposed device, no new issues of safety or effectiveness are presented.

Substantial Equivalence (SE) Comparison Table		
	NovaBone Products, LLC NovaTape / NovaPlug	**ACE RCT / RCP Collagen Topical Wound Dressing-Oral**
510(k) #	K142712	K040403
Intended Use	Temporary topical wound dressing for oral wounds and sores.	Temporary topical wound dressing for oral wounds and sores.
Target Population	Individuals requiring acute or short-term dressings for protection of oral wounds	Individuals requiring acute or short-term dressings for protection of oral wounds
Where Used	Intended for hospital, clinic, or dental office use	Intended for hospital, clinic, or dental office use
Indicated Sites	• Denture sores • Oral Ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical wounds • Traumatic wounds	• Denture sores • Oral Ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical wounds • Traumatic wounds
Preparation	No preparation required.	No preparation required.
Application	Can be applied directly to the site.	Can be applied directly to the site.
Material	Crosslinked collagen from - Bovine Hide	Crosslinked collagen from - Bovine Tendon
Device Action	On application, the dressing absorbs local wound fluids to maintain a moist wound environment to aid wound healing.	On application, the dressing absorbs local wound fluids to maintain a moist wound environment to aid wound healing.
Performance[1]	Resorbs within approximately 14 days.	Resorbs within approximately 14 days.
Biocompatible	Biocompatible*	Biocompatible
Mechanical	Wound covering only; no mechanical performance characteristics.	Wound covering only; no mechanical performance characteristics.
Package Format	Provided Sterile Single Barrier Format	Provided Sterile Single Barrier Format
Device Forms	Tape & Plug	Tape & Plug
Sterilization	E-beam irradiation / SAL 10^{-6}	Gamma irradiation / SAL 10^{-6}
Voluntary Standards met	No applicable standards	No applicable standards
*The following statement is provided in the Package Insert (Warnings): "Denatured collagen in the wound dressing has the potential to illicit an immune response."		

[1] Report SVT14-03 on file at NovaBone Products, LLC.

Collagen Material Safety

The proposed NT/NP and predicate devices are comprised of collagen derived from animal sources. All collagen used for the production of NT/NP devices is obtained from a single source, from a geographical BSE Risk I, or GBR I country. The GBR I designation is the lowest risk rating, indicating the potential for one or more animals to infected with BSE agents as "Highly Unlikely". Whereas NT/NP and the predicate are both sourced from Geographical BSE Risk I collagen, no new issues of safety are presented by the type of bovine material utilized. It has been established that the manufacturing processes used for NT/NP have sufficient viral inactivation capacity.

Because of the safeguards established to mitigate BSE risk in the bovine herds and the viral inactivation capacity of the manufacturing steps, no new issues of safety are presented for the collagen used to manufacture NT/NP devices as compared to that of the predicate.

Biocompatibility

Like the predicate devices (K040403), the proposed NT/NP devices are intended to be permanent implants that resorb over time. Biocompatibility tests in accordance with ISO 10993 (cytotoxicity, genotoxicity, irritation, sensitization, systemic toxicity (4-week), system toxicity (13-week), endotoxin, and exotoxin) were conducted on the proposed NT/NP devices and the results did not raise any issues of biological safety for the device material.

Performance – Bench Testing

The following tests were conducted to evaluate the properties of the NT/NP device components: sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE), Circular Dichroism (CD), Differential Scanning Calorimetry (DSC), Collagenase Digestion, Absorption Capacity, Percent Porosity, EDC (and NHS Residuals, Extent of Cross-linking, and Sulfide Evaluation.

Performance - Animal Testing

The NovaPlug device was evaluated in a porcine (minipig) model to evaluate the local reaction and material absorption as compared to the predicate device (K040403). The study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). The NovaPlug results are considered representative of NovaTape since the collagen, cross-linking and manufacturing processes are equivalent and differ only in final casting, cutting and pressing.

Based on the similarity and frequency of the histologic findings, the mean group implant site scores, and the absence of statistically significant differences between treatments there was no difference in responses to the NovaPlug 510(k) subject device and the predicate (K040403) device. The resorption and reaction of the NovaPlug and predicate device materials were substantially equivalent and the 510(k) subject device material completely resorbed within approximately fourteen (14) days of implantation.

Based on the results of the oral minipig implantation study, the NovaTape/NovaPlug 510(k) subject device is substantially equivalent to the predicate (K040403) when used as an oral wound dressing.

Mechanical

NT/NP devices are not intended to be load bearing. Mechanical testing comparisons are therefore not relevant to a substantial equivalence determination.

How Supplied

The proposed NovaTape/NovaPlug (NT/NP) devices are supplied sterile, in a single-barrier packaging configuration similar to the predicate device (K040403).

The device is provided in two forms, thin rectangular sheets of two sizes, (25mm x 75mm x 1mm and 20mm x 40mm x 3mm) and small cylindrical plugs (10mm diameter x 20mm length). The materials and processing methods are similar between the two device forms, varying only in the compression and cutting process used to fabricate the tape forms.

The different device shapes are solely to aid in device placement as wound dressings. The devices are both flexible and compressible and may be cut or trimmed to meet the user's needs.

All the devices are terminally sterilized to a sterility assurance level (SAL) of 10^{-6}. NT/NP devices are sterilized via e-beam radiation whereas the predicate is sterilized by gamma irradiation. E-beam radiation is used for the NT/NP devices to preserve handling properties that may be modified by other forms of sterilization. Because the device packaging and sterility assurance level are equivalent, no new issues of safety of effectiveness are presented by the packaging and sterilization methods used for the proposed NT/NP devices. An initial shelf life of twelve (12) months is supported by real-time stability studies.

Conclusion:

NovaTape and NovaPlug Dental Collagen Wound Dressings are similar to the predicate device (K040403), Collagen Topical Wound Dressing – Oral that was cleared for marketing by FDA on May 10, 2004 and marketed under as ACE Resorbable Collagen Tape (RCT) and Plug (RCP).

In vivo performance testing (porcine oral model) and biocompatibility testing were conducted on the 510(k) subject device. In the porcine oral model, the proposed device performed in an equivalent manner to the K040403 ACE predicate.

Therefore, the NovaPlug / NovaTape devices are substantially equivalent to the K040403, Collagen Topical Wound Dressing – Oral when used for the specified indications for use.